

Presentation to the Washington State Legislature

Genetic Privacy, Discrimination, and Research in Washington State: Findings, Conclusions, and Recommendations of the Washington State Board of Health Genetics Task Force

January 13, 2003
Wenatchee, WA
Linda Lake, GTF Chair
Maxine Hayes, GTF Member
Candi Wines, GTF Staff



GTF Charge

The state board of health shall convene a broadly-based task force to review the available information on the potential risks and benefits to public and personal health and safety, and to individual privacy, of emerging technologies involving human deoxyribonucleic acid (DNA).

(Engrossed Substitute Senate Bill 6153 Section 220.8)

GTF Charge

The task force shall consider information provided to it by interested persons on:

- (a) The incidence of discriminatory actions based upon genetic information;
- (b) Strategies to safeguard civil rights and privacy related to genetic information;
- (c) Remedies to compensate individuals for inappropriate use of their genetic information; and
- (d) Incentives for further research and development on the use of DNA to promote public health, safety, and welfare.

(Engrossed Substitute Senate Bill 6153 Section 220.8)

GTF Members and Affiliations

Robin Bennett, MS, CGC

Representing: Genetic Counselors

Philip L. Bereano, JD

Representing: The American Civil Liberties Union

Wylie Burke, MD, PhD

Representing: Genetics and Medical Ethics

Peter Byers, MD

Representing: Research Geneticists

Maureen Callaghan, MD

Representing: Washington State Medical Assoc.

Howard Coleman

Representing: Biotechnology Industry

Amanda DuBois, JD

Representing: Trial Attorneys

Joe Finkbonner, RPh, MHA

Representing: Washington State Board of Health

Nancy Fisher, MD, MPH, RN

Representing: Health Insurance Carriers

Maxine Hayes, MD, MPH

Representing: State Public Health

Vicki Hohner, MBA

Representing: HIPAA Privacy Experts

Mellani Hughes, JD

Representing: Private Purchasers of Medical Care

GTF Members and Affiliations

Linda Lake

Representing: Washington State Board of Health

Helen McGough

Representing: Institutional Review Boards

Robert Miyamoto

Representing: Parents of children helped by genetic testing

Suzanne Plemmons, RN, MN, CS

Representing: Local Public Health

Ree Sailors

Representing: Public Purchasers of Medical Care

Julie Sando

Representing: Citizens who have undergone genetic testing

Julie Sanford-Hanna, PhD

Representing: Pathologists or Laboratory Medicine

C. Ronald Scott, MD

Representing: Medical Research Institutions

Brenda Suiter

Representing: Hospitals

Ty Thorsen

Representing: Privacy Advocates, ACLU-WA

Meeting Topics and Presenters

January 3, 2002

- ◆ Overview of work plan Roberta Wines
- ◆ Review of legislative history Joan Mell, JD
- ◆ Legislative context for charge to the GTF Sen. Franklin, Rep. O'Brien
- ◆ Introduction to genomics Dave Eaton, PhD, Wylie Burke, MD, PhD
- ◆ Newborn Screening Program Debra Lochner-Doyle, MS, CGC
- ◆ HIPAA and genetic privacy Vicki Hohner, MBA
- ◆ Washington State Health Care Information Act Joan Mell, JD
- ◆ Institutional Review Board policies and guidelines Helen McGough

Meeting Topics and Presenters

February 25, 2002

- ◆ Overview of pertinent insurance laws and policies Jon Hedegard
- ◆ Overview of genetic privacy and discrimination Philip Bereano, JD
- ◆ Historical perspectives on eugenics Nancy Fisher, MD
- ◆ Health insurance practices and policies Nancy Fisher, MD
- ◆ Review of genetics related privacy and discrimination legislation in other states Mary Ferguson, PhD
- ◆ Overview of the effects of genetics privacy legislation on research in Oregon Roberta Wines
- ◆ Evidence of genetic discrimination and privacy violations in Washington State Mary Clogston



Meeting Topics and Presenters

April 12, 2002

- ◆ **Academic/Basic Science Panel**

Kenneth Thummel, PhD, Jonathan Tait, MD, PhD

- ◆ **Public Health Panel**

Maxine Hayes, MD, MPH, Karen Edwards, PhD, Amy Klein, MPH

- ◆ **Biotechnology Industry Panel**

Eric Earling, Steve Gilbert, PhD, Bruce Montgomery, MD



GTF Subcommittees

Subcommittee One, Chair: C. Ronald Scott, MD

The use of genetic information for health care including the diagnosis of symptomatic patients, reproductive decision-making, and predictive genetic testing for low penetrant genetic disorders

Subcommittee Two, Chair: Maxine Hayes, MD, MPH

State mandated DNA collection and testing



GTF Subcommittees

Subcommittee Three, Chair: Peter Byers, MD

The use of genetic information for research purposes

Subcommittee Four, Chair: Mellani Hughes, JD

The use of genetic information for social purposes such as insurance and employment

Examples of Existing Legislation Reviewed by the GTF

- ◆ Uniform Health Care Information Act (Chapter 70.02 RCW)
- ◆ Release of Records for Research (Chapter 42.48.050 RCW)
- ◆ Washington Law Against Discrimination (Chapter 49.60 RCW)
- ◆ Patient's Bill of Rights (ESSB 6199; Chapter 5, Laws of 2000)
- ◆ HIPAA Privacy Rules
- ◆ Americans with Disabilities Act
- ◆ The Protection of Human Subjects Regulations (45 CFR 46 and 21 CFR 50)
- ◆ The federal DNA Identification Act (1994)



GTF Products



Genetic Privacy and Genetic Discrimination Matrix for Washington State

Glossary

Recommendations

Genetic Privacy and Genetic Discrimination Matrix for Washington State

Key questions

- Encompasses/Defines Genetic Information?
- Requires Authorization for the Release of Genetic Information?
- Regulates the Use of Genetic Information by: Health Insurance Companies or Life Insurance Companies for Determining Eligibility or Setting Rates; Other Entities (e.g. banking, housing, schools) for Determining Eligibility or Setting Rates; Employers for Determining Employment Status or Health Insurance Benefits Eligibility?
- Regulatory Oversight and/or Enforcement and Penalties for Violations?

GTF Glossary

Key Terms

Confidentiality

This term is sometimes confused with the term “privacy”; however “confidentiality” is not the same thing as “privacy.” “Confidentiality” is characterized by an organizational or professional *responsibility* to protect private information; e.g. a physician has a responsibility to keep a patient’s personal health information confidential. “Privacy” is an individuals’ *right* to have information remain secret; e.g. a patient has a right to keep personal health information from being disclosed to others or made public.

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GTF Glossary



Key Terms

Discrimination

A failure to treat all alike under substantially similar conditions

Genetic Information

Information about inherited characteristics. Genetic information can be derived from a DNA-based or other laboratory test, family history, or medical examination.

GTF Recommendations

Incidence of discriminatory actions based upon genetic information

1.1 Reports of genetic testing should remain in medical records and receive the same protection as other sensitive medical information.

1.2 Support and authorize funding where necessary for efforts to educate consumers, research subjects, researchers, health care providers, employers, and insurers about how genetic information derived from genetic testing, as part of medical information, can be used, the concepts and consequences of anonymity in research, and the reporting and other mechanisms available to those who believe they have been discriminated against. These efforts should include: 1) providing information to consumers, research subjects, researchers, health care providers, employers, and insurers about existing laws and penalties for violations regarding the privacy and appropriate use of genetic information; 2) establishing a graduate program in genetic counseling at the University of Washington to address the current and future needs of the state's population.

1.3 Change the Washington Law Against Discrimination (Chapter 49.60 RCW) to explicitly include “genetic information” in the list of characteristics that receive protection under the law. The GTF recommends that “genetic information” be defined as “Information about inherited characteristics. Genetic information can be derived from a DNA-based or other laboratory test, family history, or medical examination.”^[1]

[1] Two members dissented from this recommendation.

GTF Recommendations

Strategies to safeguard civil rights and privacy related to genetic information

2.1 Adopt in rule the existing administrative policies protecting the privacy of newborn screening specimens and other tissue samples held by the state.

2.2 Create policy to make all research in the State of Washington involving genetic information obtained from human subjects subject to the standards that are in place for federally funded and/or regulated human subjects research.^[1]

^[1] One member dissented from this recommendation.

2.3 Where current law permits the collection or use of genetic information by employers or insurers, state law should require informed consent from the individual for collection, storage, disclosure, and any use of such information. Uses of such information should be restricted to those purposes for which it is collected or purposes required by law. The individual providing the information shall receive the results of any tests conducted by or for the recipient of the information.

2.4 Revise Chapter 26.04 RCW to remove the ban on first cousin marriage.



GTF Recommendations

Remedies to compensate individuals for inappropriate use of genetic information

3.1 Designate a centralized agency to receive and act on reports of discrimination based upon genetic information or violations of privacy involving genetic information.

GTF Recommendations

Incentives for further research and development on the use of DNA to promote public health, safety and welfare

- 4.1** Given the limited nature of the data provided by testing conducted for the criminal DNA database, incentives for research using this resource are not warranted.
- 4.2** Ensure that state policy requires that in all research involving genetic information from individuals, explicit voluntary consent or assent be obtained or waived as detailed in applicable law and regulations.
- 4.3** Invite all stakeholders to participate in any process to create policies addressing the use of genetic information in research.



Recommendation to the Board

The Board accepts the final report of the Genetics Task Force and forwards it to the Legislature according to the terms set forth by the legislature in the budget language creating the Genetics Task Force.